

REMARKS

I. Statement of Substance of Interview

Applicant thanks the Examiner for the telephone interview on March 9, 2009. In the interview, the Applicant explained to the Examiner what he views are the differences between Knierbein and the immediate invention. Specifically, the Applicant asserted during the interview that Knierbein does not teach a method, structure, or ability to fill a medical bag. Instead, Knierbein only teaches a method by which when it is time to withdraw liquids from the medical bag, the user breaks off the protective cap by twisting the radial wings and then inserts a withdrawal spike by screwing a coupler nut onto the threads of the upper tubular part, thus sealing the bag from leaks while withdrawing liquids. By contrast, the Applicant explained that the immediate invention teaches filling a bag, then sealing it by pinching the non circular connecting part so that the liquid cannot escape, then closing the bag with a closure part, then breaking off the closure part and inserting a withdrawal spike to withdraw the liquid.

In response to the Applicant's comments, the Examiner suggested adding structural limitations to the claims which disclose a structure for filling and a structure for pinching the pinching off part. Applicant and Examiner agreed that these structures initially appeared to be disclosed in the specification.

II. Incorporation by Reference of Prior Arguments

By way of this Response, Applicant re-asserts and incorporates by reference its prior arguments before the Office, including those arguments made in the responses submitted on October 8, 2008 and March 26, 2008.

III. Claims

Claims 1-10 are currently pending and stand rejected. By way of this Response, Claim 1 has been amended. No new matter is presented by way of this amendment. Support for the amendment can be found throughout the specification, including at page 8, lines 19-23 of the specification.

IV. Summary of the December 24, 2008 Office Action

In the December 24, 2008 Office Action, the Office set forth the following rejections:

- (a) Claims 1, 5, 6, 9, and 10 were rejected under 35 § U.S.C. 102 (a) or (e) as being anticipated by U.S. Patent No. 6,364,143 (“Knierbein”);
- (b) Claims 2-4 were rejected under 35 § U.S.C. 103(a) over Knierbein in view of U.S. Patent No. 5,494,170 (“Burns”); and
- (c) Claims 7 and 8 were rejected under 35 § U.S.C. 103(a) over Knierbein in view of U.S. Patent No. D456,507 (“LeMarr”).

V. The Rejection Under 35 U.S.C. § 102 Over Knierbein Should Be Withdrawn.

The Office rejected Claims 1, 5, 6, 9, and 10 as anticipated under 35 U.S.C. § 102 over Knierbein. To establish anticipation, the Federal Circuit has stated that it “requires the disclosure in a single prior art reference of each element of the claim under consideration.” *W.L. Gore & Assocs. v. Garlock*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983); *see also* MPEP § 2131. It is not enough, however, that the prior art reference disclose all the claimed elements in isolation. Rather, “anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim.” *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452 (Fed. Cir. 1984). Furthermore, “[t]he identical invention must be shown in as complete detail as contained in the...claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

Applicant respectfully submits that a case for anticipation has not been established as Knierbein fails to disclose each and every element of Claim 1. As amended, Claim 1 is directed to a connector which can accommodate a rod or spike for filing or withdrawal of a liquid comprising an elastically deformable pinching-off part with a noncircular cross-section. In contrast, Knierbein discloses a circular and non-elastically deformable connector. Knierbein does not describe filling the bag through this connector or pinching the connector. Instead, Knierbein only teaches a connector which can be used for withdrawing fluids. (Knierbein 3:41-54.)

As such, Knierbein fails to disclose each and every element of independent Claim 1. Accordingly, as Claims 5, 6, 9, and 10 depend from independent Claim 1, Knierbein fails to

disclose each and every element of Claims 5, 6, 9, and 10. Applicant respectfully requests the rejection under 35 U.S.C. § 102 based upon Knierbein be withdrawn.

VI. The Rejections Under 35 U.S.C. § 103 Should Be Withdrawn.

The Office rejected dependent Claims 2-4, which depend from independent Claim 1, as obvious under 35 U.S.C. § 103 over Knierbein in view of Burns. The Office also rejected dependent Claims 7 and 8, which depend from independent Claim 1, as obvious under 35 U.S.C. § 103 over Knierbein in view of LeMarr. Applicant respectfully submits that no *prima facie* case of obviousness has been established because the Office has not demonstrated that the references, regardless if combined, teach or suggest all of the limitations of the claimed invention.

To establish a *prima facie* case of obviousness, three basic criteria must be met. M.P.E.P. § 2143. First, there must be an apparent reason why a person of ordinary skill would have combined the prior art elements in the manner claimed. *KSR Int'l v. Teleflex, Inc.*, 127 S.Ct. 1727, 1741 (2007). Second, there must be a reasonable expectation of success. See Exam. Guidelines for Determining Obviousness Under 35 U.S.C. 103 in view of *KSR Int'l Co. v. Teleflex, Inc.*, 72 Fed. Reg. 57530 (Oct. 10, 2007). Third, the references, when combined, must teach or suggest all the claim limitations or the Office must explain why the shortcomings of the prior art would have been obvious. *Id.* at 57528.

The burden of establishing a *prima facie* case of obviousness lies with the Office. In determining obviousness, one must focus on the invention as a whole. *Symbol Technologies Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1577-78, 19 U.S.P.Q. 2d 1241 (Fed. Cir. 1991). The primary inquiry is: “[w]hether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have had a reasonable likelihood of success ... Both the suggestion and the expectation of success must be found in the prior art, not the applicant’s disclosure.” *In re Dow Chemical*, 837 F.2d 469, 473, 5 U.S.P.Q. 2d 1531 (Fed. Cir. 1988).

In addition to its discussion on Knierbein, the Office submits that Burns discloses a snap fit and a self-sealing membrane. The Office also submits that LeMarr discloses a nebulizer vial comprising an arrow designed as a recess and/or as a raised structure that shows the user where the fluid will exit the container when opened. Finally, the Office submits that it would have been

obvious for one of ordinary skill in the art to combine the teachings of Knierbein with Burns or LeMarr.

As previously discussed, Knierbein fails to teach or suggest each and every element of independent Claim 1. Specifically, Knierbein fails to teach a connecting part which can accommodate a rod or spike for filling. Moreover, Knierbein teaches away from the present claims as its teachings require the use of a non-deformable connector with a circular cross-section, while Claim 1 teaches a deformable connector with a non-circular cross-section. To withdraw liquids, Knierbein describes first removing a protective cap from the connector by twisting off the protective cap using its radially protruding wings. (Knierbein 3:50-54.) Breaking off the protective cap leaves the tubular upper part of the connector intact and exposes the connector's external threading. (Knierbein 3:41-43.) A coupler nut with a withdrawal spike is then screwed onto the threading of the tubular upper part of the connector so that liquid can be withdrawn through the spike. (Knierbein 4:7-14.) These limitations require that the tubular upper part of the connector be circular and non-elastically deformable. If the tubular upper part is not circular, then the coupler nut cannot be screwed onto it as described. (Knierbein 4:7-14.) If the tubular upper part is elastically deformable, then it would not be able to form the seal as claimed. (Knierbein Claim 1.) Therefore, to conform with Knierbein's specification and claims, the tubular upper part of the connector must be circular and non-elastically deformable.

Burns and LeMarr both fail to teach or suggest these limitations of Claim 1 in the pending Application. Specifically, the use of the non-circular, elastically deformable connecting part has benefits not contemplated in Burns or LeMarr. The elastic deformability of the connecting part eliminates the danger of liquid escaping the packaging after filling. (*See* Appl. at 2:33-37.) In addition, the elastic deformability of the connector part allows the packaging to be filled in a horizontal position, which is particularly useful when large-volume bags are filled. (*Id.* at 3:1-4.) In contrast, Burns contemplates an inflexible circular container closure with a stopper and shield combination that are used to maintain a vacuum in the container to enable bodily fluid collection. Similarly, LeMarr contemplates an ornamental design for a nebulizer vial with an arrow at one end. As such, one of ordinary skill in the art, when reading Knierbein in view of LeMarr or Burns would not be taught or suggested to develop a connecting part that can accommodate a rod or spike for liquid filling or withdrawal that is non-circular and

elastically deformable with minimal pressure such that it re-assumes its original shape after pinching.

Therefore, even if LeMarr, Burns and Knierbein were combinable, which Applicant denies, Applicant submits that such a combination fails to teach or suggest all the elements of independent Claim 1. Claims 2-4, 7, and 8 depend from independent Claim 1. Accordingly, Applicant submits that LeMarr, Burns and Knierbein fail to teach or suggest Claims 2-4, 7 and 8. Based on the above, Applicant respectfully requests that the Office's rejection of Claims 2-4 as obvious under 35 U.S.C. § 103(a) over Knierbein in view of Burns be withdrawn. The Applicant similarly respectfully requests that the Office's rejection of Claims 7 and 8 as obvious over Knierbein in view of LeMarr be withdrawn.

CONCLUSION

For at least the foregoing reasons, it is respectfully submitted that Claims 1-10 are in condition for allowance. Early and favorable consideration is respectfully requested, and the Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution.

Further, none of Applicant's amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicant reserves all rights to pursue any such subject matter in this or a related patent application.

Respectfully submitted,



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